



TULSA DENTAL PRODUCTS

Shaping The Future of Endodontics™

K964174

J. Safe Medical Devices Act of 1990 Summary of Safety and Effectiveness:

Submitted by: Tulsa Dental Products
Russ Vanderslice
5001 East 68th Street, Suite 500
Tulsa, OK 74136

FEB 10 1997

A. Classification Names and Numbers: Dental Cement (other than zinc oxide-eugenol), 76EMA, CFR 872.3275.

B. Common/Usual Names: Dental Cement

C. Proprietary Name: Mineral Trioxide Aggregate (MTA)

D. Establishment Registration Number: 1643003

E. Classification: This device can be classified as a Class II device: ~~Dental Cement~~ (other than zinc oxide-eugenol), 76 ~~EMA~~, CFR ~~872.3275~~.
KEF 9/2/820 PLS 1/30/97

F. Performance Standard: Performance standards have not been established.

G. Description of the Device: Mineral Trioxide Aggregate (MTA) is a cement-like substance which seals off all pathways of communication between the root canal system and the external surface of the tooth. Indicated clinical applications include use as repair of pulpal exposures. The powder consists of fine hydrophilic particles which set in the presence of moisture. Hydration of the powder results in a colloidal gel which solidifies to a hard structure.

Mineral Trioxide Aggregate is biocompatible, and exhibits significantly better adaptation to dentinal walls than other materials. It possesses a high degree of sealability; the presence or absence of blood does not affect its sealing ability. Setting time after hydration and application is approximately three hours. In tests, its compressive strength at 21 days is about 70 Mpa. Use of MTA requires only the appropriate hydration of the powder to a viscous consistency. The mixture can then be placed over the exposure site and gently patted into place using a moistened cotton ball if necessary.

H. Determination of Substantial Equivalence Process: This product has the same intended use as similar products currently cleared for marketing by the 510(k) process for the purpose of repairing pulpal exposures. The technological characteristics for this product are substantially equivalent as those of similar products, used for identical purposes, currently on the market. We believe that sufficiently precise specifications for this material from which this product is constructed have been supplied.

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Corporate Headquarters
5001 East 68th Street, Suite 500
Tulsa, OK 74136-3332
1-800-379-3432
(918) 493-6598
Fax: (918) 493-6599

Manufacturing
3111 Hanover Road
Johnson City, TN 37604
1-800-669-0822
(423) 282-1453
Fax: (423) 282-1995

Distribution
3213 Hanover Road
Johnson City, TN 37604
1-800-474-0298
(423) 282-8114
Fax: (423) 282-8661